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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/159,172	09/23/1998	FRANCIS A. ENNIS	UMMC98-13	4830

21005 7590 06/24/2002

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/24/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.



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19

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/9/01, 2/28/02

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 4-8, 11, 17, 20-22 is/are pending in the application.
Of the above, claim(s) 1, 4-8, 11, 17, 20-22 is/are withdrawn from consideration.
- ☐ Claim(s) 1, 4-8, 11, 17, 20-22 is/are allowed.
- ☒ Claim(s) 1, 4-8, 11, 17, 20-22 is/are rejected.
- ☐ Claim(s) 1, 4-8, 11, 17, 20-22 is/are objected to.
- ☐ Claim(s) 1, 4-8, 11, 17, 20-22 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d):
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been:
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGES—

Art Unit: 1644

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/9/01 has been entered.

Claims 1, 4-8, 11, 17 and 20-22 are pending and under examination.

Claims 1, 4-8, 11, 17 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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10/8/03
Claims 1 and 11 are unclear in the preamble. It is not clear as to whether "a defined T-cell epitope" is a single epitope, common to all of the members of the group of vaccines, or whether this is a unique epitope for each of the members of the group.

In claim 1, part (b) "defined peptide" lacks antecedent basis.

Claim 7 is unclear in relation to base claim 1. It is suggested that applicant insert --level of-- and --the level of-- before "release of" and "lysis of", respectively. Applicant has made similar insertions in claim 8.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of claims 1 and 11 to recite "a defined T-cell epitope" has overcome the previously stated 103 rejection over Wisdom et al., alone or in view of Zegers et al.

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Claims 1, 4-8, 11, 17 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 11 contain new matter.

Specifically, there was no original disclosure that the candidate vaccines in the group of vaccine compositions have "a defined T-cell epitope", irrespective of whether such "defined" epitope is common to all members or is a unique epitope for each of the members of the group. By "defined T-cell epitope", it is apparent from the claim language and from applicant's remarks (in Paper 14, at pages 7-9) that applicant means a "predefined" epitope, the identity of which is known at the start of the claimed assessing method. This concept is not conveyed in the specification (the term "defined T-cell epitope" cannot be found, in relation to the candidate vaccine to be tested anywhere) or in the original claims. To the contrary the vaccine compositions contemplated (pages 14-15) and exemplified are merely conventional vaccines (see especially page 14, lines 24-25), such as attenuated strains, killed pathogens, coats, membranes, protein or portions thereof for which no T-cell epitope localization or defining has been conducted prior to the claimed assay steps. Applicant has thus introduced new matter to overcome the prior art.

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Of the references newly submitted in the IDS filed on 10/9/01 (Paper 15) the examiner considers Tal et al. to show the closest prior art. --especially at cols. 3 and 10-12. A new ground of rejection follows.

Claims 1, 5-8, 11, 17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tal et al. (5,763,284) in light of Sette et al. (Nature 328, 397, 1987).

Tal et al. show an assay essentially corresponding to the instantly claimed assays.

Tal not applicable
Candidate fusion peptides are contacted with APCs, then with T-cell hybridomas isolated from a mammal, including humans. IL-2 production or proliferation of the T-cell is assessed as a response. While the assay disclosed at col. 10, line 34 - col. 12, line 18 refer to assays for candidates which can modulate (suppress) an undesired immune response, Tal et al. disclose that *See* *09/782,709* like assays can also be used to screen fusion polypeptides to be used in vaccines (col. 12, lines 18-21). In Examples 9-10 the exemplified polypeptide has a defined T-cell epitope, as shown by Sette et al. therefore candidate vaccines with defined T-cell epitopes would have been obvious. The concluding step of instant claim 1 is conventional for assessing potential vaccines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

May 28, 2002

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182

1644